SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement is entered into between the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS) (collectively, the United States), John David Foster (the Relator), and Pfizer Inc, Warner-Lambert Company (Warner-Lambert), and Parke-Davis Division (collectively, Pfizer), hereafter referred to as "the Parties," through their authorized representatives.

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

- A. Pfizer is a corporation organized under the laws of the state of Delaware. Its headquarters are in New York. Pfizer is a manufacturer of pharmaceutical products. Parke-Davis and Warner-Lambert, were predecessor organizations that ultimately were merged into Pfizer Inc in June 2000. At all relevant times, Warner-Lambert manufactured, marketed and sold a cholesterol-lowering drug, marketed under the name Lipitor.
- B. The United States contends that Warner-Lambert owed additional rebate payments under the federal Medicaid Rebate Program, 42 U.S.C. § 1396r-8, which is part of the federal Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v.
 - C. The United States contends that it has certain civil claims against Pfizer as successor

in interest under the False Claims Act, 31 U.S.C. §§ 3729-3733, other federal statutes and/or common law doctrines, for engaging in the following conduct: during the period beginning January 1999 and ending December 1999, employees of a unit of Parke-Davis, a Warner-Lambert division, offered and made payments, characterized as "unrestricted educational grants," totaling \$250,000 (\$50,000 in the First Quarter of 1999 characterized as "program funding", \$200,000 in the Second Quarter of 1999 characterized as an "unrestricted educational grant") to the Ochsner Health Plan (Ochsner), a managed care organization headquartered in New Orleans, Louisiana, in exchange for Ochsner's agreement to extend unrestricted formulary-status to Lipitor in order to encourage Ochsner plan doctors to write Lipitor prescriptions for Ochsner plan beneficiaries. In addition, Ochsner agreed to extend this formulary status for three years and entered into a so-called market share contract that enabled Ochsner to receive additional discounts and rebates on the Ochsner plan's usage of Lipitor over the three year period of the agreement.

D. Prior to its acquisition by Pfizer, Warner-Lambert entered into a rebate agreement with the Centers for Medicare and Medicaid Services (CMS). The United States contends that Warner-Lambert knowingly misreported and underpaid its Medicaid Rebates for Lipitor for certain quarters, i.e., the amounts that it owed to the states under the federal Medicaid Rebate Program, 42 U.S.C. § 1396r-8. Warner-Lambert was generally required on a quarterly basis to calculate and pay rebates to each state Medicaid program based on the difference between the Average Manufacturer Price ("AMP") and its "Best Price," as defined by 42 U.S.C. § 1396r-8(k)(1) and 1396r-8(c)(1)(C). For the First, Second, Third, and Fourth Quarters of 1999, Warner-Lambert misreported and underpaid its Medicaid rebates to states participating in the

Medicaid Rebate Program by calculating its Best Price for Lipitor without factoring in the value of all unrestricted educational grants and rebates that were, in fact, discounts off the purchase price of Lipitor, which were not disclosed to the states or the federal government. By failing to disclose and properly report these discounts, Warner-Lambert was in breach of its Medicaid Rebate Agreement with CMS and was unjustly enriched by maintaining possession of the rebate funds that were rightfully and statutorily owed to the Medicaid Rebate Program (hereinafter referred to as the "Covered Conduct").

E. The United States also contends that it has certain administrative claims against Pfizer under the provisions for permissive exclusion from the Medicare, Medicaid and other federal health care programs, 42 U.S.C. § 1320a-7(b), and the provisions for civil monetary penalties, 42 U.S.C. § 1320a-7a, for the Covered Conduct.

F. John David Foster, the Relator, filed a qui tam complaint (the Original Complaint) against Pfizer on May 4, 2000, which is styled United States ex. rel John David Foster v.

Warner-Lambert, Parke-Davis, and Pfizer Inc, No.1:00-cv-00246 (E.D. Texas). The Original Complaint included not only the allegations set forth in the Covered Conduct, described herein, but also asserted allegations regarding other alleged Pfizer payments. On February 5, 2002, Relator filed a Second Amended Complaint containing not only the allegations in the Original Complaint, but also new and distinct allegations from those contained in the Original Complaint. These new and distinct allegations are hereinafter referred to as the "Amended Complaint Allegations" and are not hereby released.

G. The Parties desire a final negotiated settlement and compromise of the claims against Pfizer set forth in Paragraph D and in the Original Complaint.

- H. Warner-Lambert denies the contentions of the United States as set forth in Paragraph D above and the allegations set forth in the Original Complaint and denies that it has any liability relating to these contentions and allegations. This Settlement Agreement does not constitute an admission by Warner-Lambert of any liability or wrongful conduct. All Covered Conduct, described herein, occurred prior to the June 2000 merger into Pfizer Inc.
- I. In order to avoid the delay, uncertainty, inconvenience and expense of protracted litigation of these claims, the Parties reach a full and final settlement as set forth below.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in consideration of the mutual promises, covenants, and obligations set forth below, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. Pfizer agrees to pay to the United States and the individual States the total amount of \$49,000,000 (the "Settlement Amount") as follows: Pfizer agrees to make payment to the United States of \$49,000,000 (which includes both the United States' and the States' shares of the Settlement Amount) by electronic funds transfer into an Escrow Account pursuant to written instructions to be provided by either T. Reed Stephens, Trial Attorney, Commercial Litigation Branch or Michael Lockhart, Assistant United States Attorney, and pursuant to the Escrow Agreement, attached hereto as Exhibit A. Pfizer agrees to make this electronic funds transfer to the Escrow Account no later than forty-eight (48) hours after the last signature of the last signatory on this Agreement. However, such funds shall not be released from the Escrow Account except according to the terms of the Escrow Agreement and Paragraph 26 of this Settlement Agreement.

- 2. Within a reasonable period of time after the receipt of the payment described in Paragraph 1 above and after the Effective Date of this Settlement Agreement, the United States agrees to pay not less than 20% and not more than 21.3% of the federal share of the Settlement Amount plus accrued interest from the Escrow Account to the Relator as his share of the proceeds pursuant to 31 U.S.C. § 3730(d).
- 3. The Relator agrees that this settlement is fair, adequate, and reasonable under all circumstances, and will not challenge the Settlement Agreement pursuant to 31 U.S.C. § 3730(c)(2)(B), and expressly waives the opportunity for a hearing on any such objection, pursuant to 31 U.S.C. § 3730(c)(2)(B).
- 4. Subject to the exceptions in Paragraph 6 below, in consideration of the obligations of Pfizer set forth in this Settlement Agreement, conditioned upon Pfizer's payment in full of the Settlement Amount, the United States (on behalf of itself, its officers, agents, agencies and departments) agrees to release Pfizer, including its predecessors, successors, subsidiaries and affiliates, and assigns, as well as its current officers, directors, employees, and agents (Pfizer Released Parties) from any civil or administrative monetary claim the United States has or may have under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; the Medicaid Rebate statute, 42 U.S.C. § 1396r-8; or the common law theories of unjust enrichment, disgorgement, restitution, recoupment, breach of contract and fraud, for the Covered Conduct.
- 5. In consideration of the obligations of Pfizer set forth in this Settlement Agreement and the Corporate Integrity Agreement (CIA) incorporated by reference, conditioned upon Pfizer's payment in full of the Settlement Amount, the OIG-HHS agrees to release and refrain from

instituting, directing or maintaining any administrative claim or any action seeking exclusion from the Medicare, Medicaid or other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Pfizer, including its predecessors, successors, subsidiaries and assigns, under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law), or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks and other prohibited activity), for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 6, below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Pfizer from the Medicare, Medicaid or other Federal health care program under 42 U.S.C. § 1320a-7(a)(mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which civil claims have been reserved in Paragraph 6, below.

- 6. Notwithstanding any term of this Settlement Agreement, specifically reserved and excluded from the scope and terms of this Settlement Agreement as to any entity or person (including without limitation Pfizer) are any and all of the following claims of the United States:
- (a) Any civil, criminal or administrative claims of the United States arising under Title 26, U.S. Code (Internal Revenue Code);
 - (b) Any criminal liability;
- (c) Except as explicitly stated in this Settlement Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;
- (d) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
 - (e) Any claims based upon such obligations as are created by this Settlement

Agreement;

- (f) Any express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services, provided by Pfizer;
- (g) Any claims of the United States based on a failure to deliver items or services due;
- (h) Any civil or administrative claims against individuals, including current or former directors, officers, employees, agents or shareholders of Pfizer who receive written notification that they are the target of a criminal investigation (as defined in the United States Attorneys' Manual), are criminally indicted or charged, or are convicted, or who enter into a criminal plea agreement related to the Covered Conduct; and
- (i) (Other than false claims or reverse false claims that arise directly from the misreporting of Best Price as a result of payments by Pfizer or its subsidiaries, Parke-Davis or Warner-Lambert, to the Ochsner Health Plan), Any false claims or reverse false claims arising from conduct occurring in the Third and/or Fourth calendar Quarters of 1999 or conduct affecting Pfizer's Best Price reporting obligations for the Third and/or Fourth calendar Quarters of 1999 if the government intervenes in the Amended Complaint as to the Relator's allegations relating to Lipitor's Medicaid Drug Rebate Best Price for the Third and Fourth Quarters of 1999.
- 7. Pfizer waives and will not assert any defenses Pfizer may have to any criminal prosecution or administrative action relating to the Covered Conduct, which defenses may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this settlement bars a remedy sought in such criminal prosecution or

administrative action. Pfizer agrees that this settlement is not punitive in purpose or effect.

Nothing in this paragraph or any other provision of this Settlement Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue Laws, Title 26 of the United States Code.

- 8. In consideration of the obligations of the Relator set forth in this Settlement Agreement, Pfizer, on behalf of itself, its employees, agents, successors and assigns, fully and finally releases, acquits, waives, and forever discharges the Relator, his successors and assigns, agents and attorneys, as well his agents from any and all rights, claims, expenses, debts, liabilities, demands, obligations, costs, damages, injuries, actions and causes of action of every nature, whether known or unknown, suspected or unsuspected, in law or equity, arising from (A) Medicaid Rebate Program violations for Lipitor for the First and Second Quarters of 1999; (B) Medicaid Rebate Program violations for Lipitor in connection with undisclosed discounts to Ochsner for the Third and Fourth Quarters of 1999; and (C) all other Medicaid Rebate Program violations for Lipitor for the Third and Fourth Quarters of 1999 in the event the government declines to intervene in the Second Amended Complaint as to these quarters.
- 9. The Relator fully and finally releases the United States, its agencies, employees, servants, and agents from any claims which the Relator has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, relating to the Covered Conduct or arising from the filing of the Original Complaint as to Pfizer, including any claim for a share of the proceeds of this Settlement Agreement pursuant to 31 U.S.C. § 3730(d) and (c).
 - 10. Pfizer fully and finally releases the United States, its agencies, employees, servants,

and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which Pfizer has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

- 11. Except as enumerated below, in consideration of the obligations set forth in this Settlement Agreement, the Relator, on behalf of himself, his agents, successors and assigns, hereby releases, acquits, waives, and forever discharges the Pfizer Released Parties, from any and all claims, whether known or unknown, whether suspected or unsuspected, without any limitation or restriction that Relator or any person or entity acting for him or on his behalf ever had, now have or hereafter can, shall or may have against the Pfizer Released Parties up until the Effective Date of this Settlement Agreement for:
 - A. Medicaid Rebate Program violations for Lipitor for the First and Second Quarters of 1999;
 - B. Medicaid Rebate Program violations for Lipitor in connection with undisclosed discounts to Ochsner for the Third and Fourth Quarters of 1999; and
 - C. All other Medicaid Rebate Program violations for Lipitor for the Third and Fourth Quarters of 1999 in the event the government declines to
 - intervene in the Second Amended Complaint as to these quarters.

This Global Release shall not apply to the following enumerated claims, as well as any other claim not specifically released:

i. Attorneys' fees and cost authorized by 31 U.S.C. § 3730(d);

- ii. Relator's retaliatory discharge claim contained in his Second Amended Complaint;
- iii. False Claims Act violations related to Lipitor in any year other than 1999; and
- iv. False Claims Act violations for any drug other than Lipitor.
- 12. The amount that Pfizer must pay pursuant to any applicable provision of this

 Settlement Agreement will not be decreased as a result of the denial of claims for payment now
 being withheld from payment by any Medicare Carrier or Intermediary or any State payor, related
 to the Covered Conduct. Pfizer agrees not to resubmit to any Medicare Carrier or Intermediary
 or any State payor any previously denied claims related to the Covered Conduct and agrees not to
 appeal any such denials of claims. Notwithstanding anything to the contrary, Pfizer does not
 submit such claims.

13. Pfizer agrees to the following:

(a) Unallowable Costs Defined: that all costs (as defined in the Federal Acquisition Regulations (FAR) § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf on Pfizer, its present or former officers, directors, employees, shareholders, and agents in connection with: (1) the matters covered by this Settlement Agreement; (2) the United States' audit and civil investigation of the matters covered by this Settlement Agreement; (3) Pfizer's investigation, defense, and any corrective actions undertaken in direct response to the United States' audit and civil investigation in connection with the matters covered by this Settlement Agreement (including attorney's fees);

- (4) the negotiation and performance of this Settlement Agreement, (5) the payment Pfizer makes to the United States pursuant to this Settlement Agreement and any payments that Pfizer may make to relator; (6) the negotiation of the CIA, and the obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in the CIA; and (ii) prepare and submit reports to the OIG-HHS, are unallowable costs on Government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP). However, nothing in this subparagraph that may apply to compliance costs affects the status of costs that are not allowable based on any other authority applicable to Pfizer. (All costs described or set forth in this Paragraph 13(a) are hereafter, "unallowable costs").
- (b) Future Treatment of Unallowable Costs: If applicable, these unallowable costs will be separately estimated and accounted for by Pfizer, and Pfizer will not charge such unallowable costs directly or indirectly to any contracts with the United States or any State Medicaid Program, or seek payment for such unallowable costs through any cost report, cost statement, information statement, or payment request submitted by Pfizer or any of its subsidiaries to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- (c) Treatment of Unallowable Costs Previously Submitted for Payment: If applicable, Pfizer further agrees that within 60 days of the effective date of this Agreement, it will identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, VA and FEHBP fiscal agents, any unallowable costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid Program, including, but not limited to, payments sought in any cost reports, cost

statements, information reports, or payment requests already submitted by Pfizer or any of its successors or its subsidiaries, and will request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Pfizer agrees that the United States, at a minimum, will be entitled to recoup from Pfizer any overpayment plus applicable interest as a result of the inclusion of such unallowable costs on previously-submitted cost reports, information reports, cost statements, or requests for payment. Any payment due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice, and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Pfizer or any of its subsidiaries on the effect of inclusion of unallowable costs (as defined in this Paragraph) on Pfizer or any of its subsidiaries' cost reports, cost statements, or information reports. Nothing in this Settlement Agreement shall constitute a waiver of the rights of the United States to examine or reexamine the unallowable costs described in this Paragraph.

- 14. Pfizer covenants to cooperate fully and truthfully with the United States' investigation of individuals and entities not specifically released in this Settlement Agreement for the Covered Conduct. Upon reasonable notice, Pfizer will make reasonable efforts to facilitate access to, and encourage the cooperation of, their directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals, and will furnish to the United States, upon reasonable request, all non-privileged documents and records in its possession, custody or control relating to the Covered Conduct.
 - 15. Pfizer agrees to enter into a Corporate Integrity Agreement (CIA) with OIG-HHS,

which will be incorporated into this Settlement Agreement by reference. Pfizer agrees to negotiate and execute its CIA before the Effective Date of this Agreement and to implement its obligations under the CIA immediately upon execution. The United States reserves the right to rescind this Settlement Agreement if Pfizer does not execute a CIA before the Effective Date of this Agreement.

- 16. This Settlement Agreement is intended to be for the benefit of the Parties, only, and by this instrument the Parties do not release any claims against any other person or entity.
- 17. Pfizer expressly warrants that it has reviewed its financial situations and that it is currently solvent within the meaning of 11 U.S.C. Section 547(b)(3) and 548(a)(1)(A)(ii)(I), and will not become insolvent as a result of the payment obligations to the United States set forth in this Settlement Agreement. Further, the Parties expressly warrant that, in evaluating whether to execute this Settlement Agreement, the Parties (a) have intended that the mutual promises, covenants and obligations set forth herein constitute a contemporaneous exchange for new value given to Pfizer, within the meaning of 11 U.S.C. Section 547(c)(1), and (b) have concluded that these mutual promises, covenants and obligations do, in fact, constitute such a contemporaneous exchange.
- 18. Each party to this Settlement Agreement will bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement except that Relator's attorneys' fees and costs are governed by 31 U.S.C. § 3730(d).
- 19. Pfizer represents that this Settlement Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.
 - 20. This Settlement Agreement is governed by the laws of the United States. The

Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Settlement Agreement will be the United States District Court for the Eastern District of Texas except as specified below in Paragraph 22.

- 21. The Parties agree that within 10 days of the Effective Date of this Settlement
 Agreement, the United States shall notify the Court that it elects to intervene partially in United
 States ex rel. John David Foster v. Warner-Lambert, Parke-Davis, and Pfizer Inc, No.1:00-cv00246 (E.D. Texas), at least for the purpose of partially settling the allegations in the Relator's
 Original Complaint: Immediately upon the government's partial intervention, at least, for
 purposes of settlement of Relator's Original Complaint, the parties will execute a stipulation of
 dismissal with prejudice of all claims arising from Lipitor Best Price Reporting violations in the
 First and Second Quarters of 1999 and, if the United States intervenes in the Amended
 Complaint as to the Third and Fourth Quarters of 1999, all Lipitor Best Price Reporting
 violations in all Quarters of 1999 arising from payments to the Ochsner Health Plan, and if the
 United States does not intervene in the Amended Complaint as to the Third and Fourth Quarters,
 all Lipitor Best Price Reporting violations in all Quarters of 1999.
- 22. The Parties agree that any disputes arising under the CIA, which shall be incorporated herein by reference, shall be resolved exclusively through the breach and dispute resolution provisions included in that agreement. A breach by Pfizer of the CIA will not constitute a breach of this Settlement Agreement.
- 23. This Settlement Agreement and the CIA, which will be incorporated herein by reference, constitute the complete agreement between the Parties. This Settlement Agreement may not be amended except by written consent of the Parties, except that only Pfizer and OIG-

HHS must agree in writing to modification of the CIA.

- 24. The undersigned individuals signing this Settlement Agreement on behalf of Pfizer represent and warrant that they are authorized by Pfizer to execute this Settlement Agreement. The undersigned United States signatorics represent that they are signing this Settlement Agreement in their official capacities and that they are authorized to execute this Settlement Agreement.
- 25. This Settlement Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement.
- 26. The Effective Date of this Settlement Agreement is the sooner of either (1) the date the United States files with the court its Notice of Election to Intervene (or, alternatively, Election to Decline to Intervene) against Pfizer with respect to the Amended Complaint Allegations, filed February 5, 2002 or (2) the date of the settlement of the Amended Complaint Allegations, filed February 5, 2002. Upon the Effective Date, the United States will be free to withdraw the Settlement Amount from the Escrow Account in accordance with the terms of the Escrow Agreement and disburse the specified amounts to the States and to the Relator.

27. This Settlement Agreement is binding on the Parties, their transferees, heirs, successors and assigns.

THE UNITED STATES OF AMERICA

DATED:

BY:

T. REED STEPHENS

Trial Attorney

Commercial Litigation Branch

Civil Division

United States Department of Justice

DATED:	BY: _	MICHAEL LOCKHART Assistant United States Attorney Office of the United States Attorney for the Eastern District of Texas
DATED: 5/16/02	BY:	LEWIS MORRIS Assistant Inspector General Office of Counsel to the Inspector General Office of Inspector General United States Department of Health and Human Services

PFIZER INC, WARNER-LAMBERT, and PARKE-DAVIS

DATED:	BY:
	GEORGE EVANS, Esq. Counsel for Pfizer,Warner-Lambe Parke-Davis
DATED: 5/10/02	BY: LYNN SHAPIRO SNYDER, Esq. STUART GERSON, Esq. Epstein, Becker & Green Counsel for Pfizer, Warner-Lambe

JOHN DAVID FOSTER - Relator

ATED: 5-20-02

BY: JOHN MDROPHY, Esq.
WADE HOWARD, Esq.
Berg & Androphy
Counsel for Relator

DATED:

BY: On Rehalf of Relator

On Rehalf of Relator

PFIZER INC, WARNER-LAMBERT, and PARKE-DAVIS

DATED: <u>5/16/02</u>	BY: Mwg () Evr GEORGE EVANS, Esq. Counsel for Pfizer, Warner-Lambert Parke-Davis
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DATED:	BY:
	LYNN SHAPIRO SNYDER, Esq.
	STUART GERSON, Esq.
	Epstein, Becker & Green
	Counsel for Pfizer, Warner-Lamber
	Parke-Davis